K013439

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510(k) Summary of Safety and Effectiveness

JAN 14 2002

(1) **Submitter's name:** Scient'x
Submitter's address: Guyancourt, France
Contact telephone number: (512) 834-6255
Contact person: Joanna Droege
Date summary prepared: October 8, 2001

(2) **Trade or proprietary device name:** Anterior Cervical Plate System
Common or usual name: Anterior cervical plating system
Classification name: Class II

(3) **Legally marketed predicate device:** Sofamor Danek – Orion System
DePuy – DePuy Motech PEAK

(4) **Subject device description:**
The Anterior Cervical Plate System consists of multiple sized plates and screws. All components are manufactured from titanium alloy (Ti-6Al-4V) that conform to ASTM F136.

(5) **Subject device intended use:**
The Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of a solid spinal fusion in patients with neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies (DDD), trauma (i.e. fractures), tumors, deformities (i.e. kyphosis, lordosis, and scoliosis), pseudoarthrosis, spinal stenosis, and failed previous fusions.

WARNING: These devices are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

(6) **Performance data:**
The Food and Drug Administration have established no performance standards applicable to anterior cervical plating systems. However, static and fatigue compression and static torsion testing of the Anterior Cervical Plate System were performed according to ASTM F1717-96.

(7) **Basis for substantial equivalence:**
The Anterior Cervical Plate System has similar design characteristics, i.e., material, screw size, and indications, as the Orion (K973854) and PEAK System (K971730) systems distributed by Sofamor Danek and DePuy Motech, respectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 4 2002

Ms. Joanna Droege
Scient'X
c/o Encore Orthopaedics
9800 Metric Boulevard
Austin Texas 78758

Re: K013439
Trade Name: Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: October 15, 2001
Received: October 17, 2001

Dear Ms. Droege:

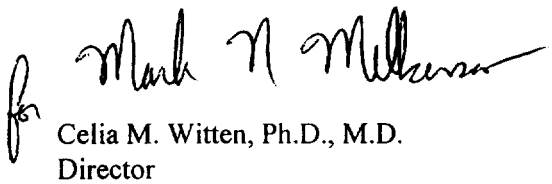
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K013439

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510(k) Number (if known): _____

Device Name: Anterior Cervical Plate System

Indications For Use:

Anterior Cervical Plate System

Indications For Use

The Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. The system is indicated for use in the temporary stabilization of the anterior spine during the development of a solid spinal fusion in patients with neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies (DDD), trauma (i.e. fractures), tumors, deformities (i.e. kyphosis, lordosis, and scoliosis), pseudoarthrosis, spinal stenosis, and failed previous fusions.

WARNING: These devices are not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhorn

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013439

Prescription Use X
(per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

OK
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